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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARK BLAND, Plaintiff, v. C.R. BARD, INC., BARD PERIPHERAL VASCULAR, INC., et al., Defendants.	Civil Action No.: **COMPLAINT AND DEMAND FOR JURY TRIAL**

PLAINTIFF'S COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff MARK BLAND (hereinafter "Plaintiff"), by and through his undersigned attorneys, hereby files this, Complaint and Demand for Jury Trial, against Defendants C.R. BARD, INC.; and BARD PERIPHERAL VASCULAR, INC. (hereinafter "Defendants"), and alleges the following:

I. PARTIES

1. Plaintiff, Mark Bland, at all times relevant to this action is and was a citizen of and resident of Baxter County, Arkansas.

2. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware with its principal place of business located at 730 Central Avenue, Murray Hill, New Jersey 07974. Bard, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold Bard IVC Filters and the Recovery® IVC Filter system to be implanted in patients throughout the United States.

3. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly-owned subsidiary corporation of Defendant C.R. Bard, with its principal place of business at 1625 West Third Street, Tempe, Arizona 85281. BPV, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold Bard IVC Filters and the Recovery® IVC Filter system to be implanted in patients throughout the United States.

4. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. are hereinafter collectively referred to as "Defendants".

5. There exists, and at all relevant times existed, a unity of interest in ownership between certain defendants and other defendants such that any individuality and separateness between the certain defendants has ceased and those defendants are the alter ego of the other certain defendants, and exerted control over those defendants.

6. Adherence to the fiction of the separate existence of these certain defendants as any entity distinct from other certain defendants would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

7. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned each of the Defendants were the agent, servant, employee, and/or joint venturer of the other co-defendants, and at all said times each Defendant was acting in the full course, scope, and authority of said agency, employment, and/or joint venture.

8. At all times herein mentioned, Defendants were engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting, and selling in interstate commerce Bard IVC Filters for use by Plaintiffs, either directly or indirectly through third parties or related entities. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for his injuries, losses, and damages.

II. JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction over this matter because the parties are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs. *See* 28 U.S.C. § 1332.

10. The Court has personal jurisdiction over the Defendants because they have sufficient minimum contacts such that asserting jurisdiction over the defendants does not offend traditional notions of fair play and substantial justice. *International Shoe v. Washington*, 326 U.S. 310, 325 (1945).

11. Venue is proper in this district because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district. *See* 28 U.S.C. § 1391(b)(2). Specifically, defendant Bard's principal place of business is in New Jersey.

III. GENERAL BACKGROUND

12. Plaintiff brings this action for serious personal injuries suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava Filter ("IVC Filter") manufactured by Bard.

13. The subject IVC filter, the Recovery® filter system, was a part of Bard's "retrievable" IVC Filter product line, which also includes the following devices: G2®, G2 Express®, Eclipse®, Meridian®, and Denali®.

14. Plaintiff's claim for damages all relate to Bard's design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Bard IVC Filters.

15. At all times relevant to this action, Bard intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

16. At all times relevant to this action, Bard intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Bard had reason to know, and/or did know, that it's IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

17. At all times relevant to this action, Bard is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

A. INFERIOR VENA CAVA FILTERS GENERALLY

18. Inferior Vena Cava ("IVC") Filters first came commercially available to the medical community in the 1960's. Throughout the years, medical device manufacturers have introduced several different designs of IVC Filters.

19. An IVC Filter, including Bard IVC Filters, are devices designed to filter blood clots that travel from the lower portions of the body to the heart and lungs. IVC Filters may be designed to be implanted, either temporarily or permanently, within the inferior vena cava.

20. The inferior vena cava is the largest vein in the human body that returns blood to the heart from the lower portions of the body. In certain people, and for various reasons, blood clots travel from vessels in the legs and pelvis, through the inferior vena cava into the lungs. Often these blood clots develop in the deep leg veins. These clots are called "deep vein thrombosis" or "DVT". Once the blood clots reach the lungs they are considered "pulmonary emboli" or "PE". Pulmonary Emboli present serious risks to human health, including death. An IVC Filter, like the Bard IVC Filters, is designed to prevent these thromboembolic events.

21. Those at risk for DVT/PE can undergo medical treatment to manage the risk. As an example, a doctor may prescribe anticoagulant medications such as Heparin, Lovenox, or Warfarin to regulate the clotting factor of the blood. In some people who are at a high risk of DVT/PE and cannot manage their conditions with medication, physicians may recommend surgical implantation of an IVC Filter to prevent thromboembolic events.

22. As stated above, IVC Filters have been on the market for decades and were permanent implants. However, use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

23. In order to increase sales of these devices, Bard sought to expand the market for prophylactic or preventative use among nontraditional patient populations that were temporarily at risk of developing blood clots. These Filters are designed so they can be surgically removed from a patient after the risk of a thromboembolic event has subsided.

24. The Recovery® Filter is an example of a retrievable filter.

B. THE RECOVERY® FILTER

i. Development and FDA Clearance

25. Defendants have distributed and marketed the Simon Nitinol Filter ("SNF") device since 1992. The SNF is a permanent filter with no option to retrieve it after implantation.

26. The SNF was initially marketed by a company known as Nitinol Medical Technologies. In late 1992, Defendants worked with Nitinol Medical Technologies on a redesign of the SNF in order to make it retrievable. On October 19, 2001, Defendants purchased the rights to manufacture, market, and sell this new, redesigned product in development at the time. This product ultimately became the Recovery® Filter.

27. Defendants sought Food and Drug Administration ("FDA") approval to market the Recovery® Filter as a *permanent* filter under § 510(k) of the Medical Device Amendment by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the SNF.

28. On November 27, 2002, Defendants received the FDA's "clearance" to market to market the Recovery® Filter as a *permanent* filter.

29. § 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more

rigorous "premarket approval" process in its amicus brief filed with the United States Court of Appeals for the Third Circuit in *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k). . . A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a [pre-market approval]). *A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective.* (Emphasis in original).

30. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-479 (1996), the Supreme Court described the 510(k) process, observing:

> If the FDA concluded on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis. . . The §510(k) notification process is by no means comparable to the [pre-market approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours. . . Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly.

31. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug . . . and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling . . ." This obligation extends to post-market monitoring of adverse events/complaints.

32. In April 2003, Defendants submitted a §510(k) premarket notification of intent to market the Recovery® Filter for the additional intended use of *optional retrieval*. In July 2003, Defendants obtained clearance from the FDA to market the Recovery® Filter for *optional retrieval*.

33. Although Defendants began aggressively marketing the Recovery® Filter in 2003, full market release did not occur until January 2004.

34. Defendants were aware that the Recovery® Filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric (weight loss) and orthopedic procedures.

ii. Recovery® Filter Design Specifications

35. The Recovery® Filter consists of two (2) levels of six (6) radially distributed NITINOL (a nickel titanium alloy with the full name of Nickel Titanium Naval Ordnance Laboratory) struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots.

36. The Recovery® Filter has six (6) short struts, which are commonly referred to as the "arms" and six (6) long struts, which are commonly referred to as the "legs".

37. Each strut is held together by a single connection to a cap located at the top of the Filter. According to the patent application for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism".

38. The alloy NITINOL possesses "shape memory", meaning that NITINOL will change shape according to changes in temperature, then retake its prior shape after returning to its initial temperature.

39. When placed in saline, the Recovery® Filter's NITINOL struts become soft and can be straightened to allow delivery through a small-diameter catheter or sheath. The NITINOL struts then resume their original shape when warmed to body temperature in the vena cava.

40. The Recovery® Filter is inserted via catheter guided by a physician (typically an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion.

iii. Inherent Risks of the Recovery® Filter

41. The Recovery® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple early studies reported that the Recovery® Filter has a fracture and migration rate ranging from 21% to 31.7%, rates that are substantially higher compared to other IVC Filters. *See* Hull JE, Robertson SW. J Vasc Interv Radiol., "Bard Recovery Filter: evaluation and management of vena cava limb perforation, fracture, and migration" 2209;20(1):52-60; *See also* Nicholson W, et al. Arch. Int. Med., "Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade" 2010 Nov.; 170:1827-31.

42. The Recovery® Filter similarly poses a high risk of tilting and perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, and ureter. All of which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the device may be irretrievable. These patients are faced with a lifetime of future risk.

43. The Recovery® Filter failures described herein occur at a substantially higher rate than other IVC Filters.

44. The Adverse Event Reports ("AERs") associated with all IVC Filters demonstrates that Bard IVC Filters are far more prone to failure than are other similar devices. A review of the

FDA MAUDE[1] database from the years 2004-2008 demonstrates that Defendants' IVC Filters are responsible for the following percentages of all IVC Filter AERs:

a. 50% of all adverse events;

b. 64% of all occurrences of migration of the IVC Filters;

c. 69% of all occurrences of vena cava wall perforation; and

d. 70% of all occurrences of filter fracture

45. These failures were often associated with severe patient injuries, such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

46. These failures and resulting injuries are attributable, in part, to the fact that the Recovery® Filter design was unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

47. In addition to design defects, the Recovery® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The

[1] The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. *See FDA, MAUDE – Manufacturer and User Facility Device Experience,* (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated June 30, 2021; last visited July 27, 2021).

presence of said "draw markings" and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery® Filter is prone to fail at or near the location of "draw markings"/circumferential grinding markings on the struts of the device. These exterior manufacturing defects render the Recovery® Filter too weak to withstand normal placement within the human body.

iv. What Defendants Knew or Should Have Known

48. Defendants knew that no clinical and bench testing was conducted to determine whether the Recovery® Filter would perform safely and effectively once implanted in the human body and subjected to normal *in vivo* stresses.

49. Once placed on the market in 2003, Defendants became aware of numerous AERs confirming events where the Recovery® Filter was fracturing post-implant and that fractured pieces and/or the entire device were migrating throughout the human body, including the heart and lungs.

50. Within the first year of full market release of the Recovery® Filter, Defendants received at least 32 AERs reporting that the Recovery® had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

51. From 2003 through 2005, Defendants received ever increasing numbers of AERs reporting the above-described failures. Defendants knew or should have known that the failure rates associated with the Recovery® Filter were substantially higher than other similar products on the market.

52. In early 2005, Defendants, without notifying consumers of the design and manufacturing flaws inherent in the Recovery® Filter, began redesigning the Recovery® Filter in

an attempt to correct those flaws. The redesigned filter is known as the G2® Filter, which stands for second generation Recovery® Filter.

53. On August 29, 2005, Defendants obtained FDA clearance to market the G2® Filter. After which, Defendants quietly stopped marketing the Recovery® Filter. However, Defendants failed to make any effort to notify consumers of the risks inherent in the use of the Recovery® Filter.

C. THE G2® FILTER

54. On August 10, 2005, Defendants submitted a §510(k) premarket notification of intent to market the G2® Filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. Defendants cited the Recovery® Filter as the substantially equivalent predicate device. Defendants stated that the differences between the Recovery® and G2® Filters were primarily dimensional and no material changes or additional components were added.

55. On August 29, 2005, the FDA cleared the G2® Filter for the same intended uses as the Recovery® Filter, except that it was not cleared for retrievable use.[2]

56. Defendants marketed the G2® Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance."

57. Moreover, Defendants again failed to conduct adequate clinical and bench testing to ensure that the G2® Filter would perform safely and effectively once implanted in the human body and subjected to normal *in vivo* stresses.

58. The G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

[2] The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

59. Furthermore, like its predicate device, the G2® Filter suffers from the same manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of said "draw markings" and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the G2® Filter is prone to fail at or near the location of the "draw markings"/circumferential grinding markings on the struts of the device. These exterior manufacturing defects render the G2® Filter too weak to withstand normal placement within the human body.

60. Thus, the G2® Filter shares similar defects and health risks as its predicate device, the Recovery® Filter.

61. Almost immediately upon release of the G2® Filter, Defendants received notice of the same series of adverse events of migration, fracture, tilt, and perforation causing the same type of harm as the Recovery® Filter.

62. The G2® Filter failures were again associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/peridcardial tamponade;

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels, and organs.

63. Defendants represent that the fracture rate of the G2® Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics

and the published medical literature), this representation does not accurately reflect the true frequency of the fractures for the G2® Filter.

64. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Defendants' vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

D. DEFENDANTS' KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS

65. Upon information and belief, Plaintiff alleges that as early as 2003, Defendants were aware and had knowledge of the fact that the Recovery® Filter was defective and unreasonably dangerous and was causing serious injury and death to patients who had received it. Similarly, Defendants were aware as early as 2005 that the G2® Filter was defective and unreasonably dangerous and was causing serious injury and death to patients who had received it.

66. Data establishes that the failure rates of the Recovery® and G2® Filters are/were exceedingly higher than the rate that Defendants have in the past, and currently continue to publish to the medical community and members of the public.

67. Moreover, Defendants were aware or should have been aware that the Recovery® and G2® Filter have substantially higher failure rates than do other similar products on the market, yet Defendants have failed to warn consumers of this fact.

68. Upon information and belief, from the time the G2® Filter became available on the market, Defendants embarked on an aggressive campaign of "off label marketing" concerning the G2® Filter. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2® Filter was safe and effective for retrievable use prior to the FDA approving the G2® Filter for retrievable use.

69. The conduct of Defendants as stated herein constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the Recovery® and G2® Filters, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Recovery® and G2® Filters from the market.

70. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the Recovery® Filter, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the Recovery® and G2® Filters.

IV. FACTUAL BACKGROUND AS TO PLAINTIFF

71. On or about March 13, 2004, Plaintiff Mark Bland was implanted with a Bard Recovery® Inferior Vena Cava Filter at Cox Medical Center in Springfield, Missouri by Martin Anbari, M.D.

72. The product identification sticker for the Bard Recovery® Filter was included in his medical records and identified the device's lot number as 07KN2864.

73. On or about August 1, 2019, Plaintiff underwent a computed tomography ("CT") scan of his abdomen and pelvis. The CT scan revealed that Plaintiff had an IVC Filter present and that some of the legs were extending outside of the inferior vena cava, one of which was abutting the aorta.

74. On or about October 31, 2019, Plaintiff underwent a procedure to remove his IVC Filter at Barnes Jewish Hospital in St. Louis, Missouri. Plaintiff's removing surgeon, upon review

of prior CT scans, determined that two (2) of the IVC Filter tines appeared to be fractured. Plaintiff's removing surgeon attempted to remove the fractured tines via alligator forceps. However, these attempts were unsuccessful as one of the tines was entirely extravascular and the other was embedded in the wall of the Plaintiff's inferior vena cava, abutting the adjacent vertebral body osteophyte.

75. Plaintiff's removing surgeon made the determination to leave the fractured tines within Plaintiff's body as intentional foreign bodies because the risk of vessel injury and injury to surrounding structures outweighed the benefit of continuing to retrieve the fractured tines.

76. The remainder of Plaintiff's IVC Filter was successfully retrieved.

77. Plaintiff will require ongoing medical care to monitor the tines in Plaintiff's body to ensure that they do not cause future injury.

78. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses.

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

79. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

80. At all times relevant to this action, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, and/or promoting, selling and/or distributing Bard IVC Filters, including the Recovery® Filter, and through that conduct has knowingly and intentionally placed Bard IVC Filters, including the Recovery® Filter, into the stream of commerce with full knowledge they reach consumers such as Plaintiff who would become implanted with them.

81. Defendants did in fact test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute Bard IVC Filters to Plaintiff, Plaintiff's prescribing health care professionals, and the consuming public. Additionally, Defendants expected that Bard IVC Filters, including the Recovery® Filter, they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did in fact reach prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from which it was initially distributed by Defendants.

82. Bard IVC Filters, including the Recovery® Filter, had potential risks and side effects that were known or knowable to Defendants by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of Bard IVC Filters.

83. Defendants knew or should have known of the defective condition, characteristics, and risks associated with Bard IVC Filters, including the Recovery® Filter. These defective conditions included, but were not limited to:

a. Bard IVC Filters posed a significant and higher risk of failure than other similar IVC Filters (fracture, migration, tilting, and perforation of the vena cava wall);

b. Bard IVC Filter failures result in serious injuries and/or death; and

c. Certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

84. Consequently, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

85. The Defendants further had a duty to warn of dangers and proper safety instructions that they became aware of even after the device was distributed and implanted in Plaintiff.

86. Bard IVC Filters, including the Recovery® Filter, were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Bard IVC Filters, such as Plaintiff, when used in an intended or reasonably foreseeable way.

87. The warnings and directions Defendants provided with Bard IVC Filters, including the Recovery® Filter, failed to adequately warn of the potential risks and side effects of Bard IVC Filters.

88. These risks and side effects as described herein were known or were reasonably scientifically knowable to Defendants.

89. However, these risks and side effects as described herein are of such a nature that ordinary consumers, including Plaintiff and Plaintiff's treating health care providers, would not have readily recognized the potential harm.

90. The Recovery® Filter was expected to and did reach Plaintiff without substantial change in its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

91. Plaintiff and Plaintiff's physicians used the Recovery® Filter, in a normal, customary, intended, and foreseeable manner.

92. Therefore, the Recovery® Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labels, and/or instructions accompanying the product.

93. As a direct and proximate result of the Defendants lack of sufficient warnings, labels, and/or instructions, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal

life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

94. WHEREFORE, Plaintiff demands judgment against the Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

95. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

96. At all times relevant to this action, Defendants designed, tested, distributed, manufactured, sold, marketed, and otherwise placed into the stream of commerce Bard IVC Filters, including the Recovery® Filter, for use by consumers, such as Plaintiff, in the United States.

97. Bard IVC Filters, including the Recovery® Filter, were expected to, and did, reach Defendants' intended consumers, including Plaintiff, without substantial change in the condition in which it was in when it left Defendants' possession.

98. At all times relevant to this action, Bard IVC Filters, including the Recovery® Filter, were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the general public and Plaintiff in particular.

99. Bard IVC Filters, including the Recovery® Filter, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that they were not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

100. Physicians, including Plaintiff's physician, implanted Bard IVC Filters, including the Recovery® Filter, as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

101. Plaintiff and Plaintiff's physician utilized the Recovery® Filter in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

102. At the time Defendants placed its defective and unreasonably dangerous Bard IVC Filters, including the Recovery® Filter, into the stream of commerce, commercially, technologically, and scientifically feasible alternative designs were attainable and available.

103. These alternative designs would have prevented the harm resulting in Plaintiff's injuries and damages without substantially impairing the reasonably anticipated or intended function of Bard IVC Filters.

104. As a direct and proximate result of the Recovery® Filter's defective design, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

105. WHEREFORE, Plaintiff demands judgment against the Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

106. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

107. At all times relevant to this action, Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold Bard IVC Filters, including the Recovery® Filter, for use in the United States.

108. At all times relevant hereto, Defendants designed, distributed, manufactured, marketed, and sold Bard IVC Filters, including the Recovery® Filter, that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

109. Upon information and belief, Bard IVC Filters, including the Recovery® Filter, contained a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

110. As a result of this manufacturer defect, the Recovery® Filter injured Plaintiff and failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner.

111. As a direct and proximate result of the Recovery® Filter's manufacturing defect, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

112. WHEREFORE, Plaintiff demands judgment against the Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together

with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV: NEGLIGENCE

113. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

114. At all times relevant to this action, Defendants were in the business of designing, developing, manufacturing, marketing, selling, and distributing sophisticated medical devices, including its Bard IVC Filters and the Recovery® Filter.

115. At all times relevant hereto, Defendants were under a duty to exercise reasonable and prudent care in the design, development, manufacture, marketing, labeling, promotion, distribution, and sale of Bard IVC Filters, including the Recovery® Filter, so as to avoid presenting an unreasonable risk of harm or injury to the Plaintiff and to those receiving their Filters.

116. Defendants knew or reasonably should have known that Bard IVC Filters, including the Recovery® Filter, were dangerous or were likely to be dangerous when used in its intended or reasonably foreseeable manner.

117. At the time of manufacture and sale of Bard IVC Filters, the Recovery® Filter included, Defendants knew or should have known that the Bard IVC Filters were designed and manufactured in a manner presenting:

a. An unreasonable risk of fracture of portions of the filters;

b. An unreasonable risk of migration of the filters and/or portions of the filters;

c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and

d. Insufficient strength or structural integrity to withstand normal placement within the human body.

118. At the time of manufacture and sale of Bard IVC Filters, the Recovery® Filter included, Defendants knew or should have known that using Bard IVC Filters, including the Recovery® Filter, in the manner in which it was intended created a significant risk of a patient suffering severe health side effects, including but not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/peridcardial tamponade;

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

119. Despite the aforementioned duty on the part of the Defendants, Defendants breached their duty to exercise reasonable and prudent care in the design, development, manufacture, marketing, labeling, promotion, distribution, and sale of Bard IVC Filters, including the Recovery® Filter, by, among other things, the following acts or omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC Filters available for the same purpose;

c. Failing to perform reasonable pre- and post-market testing of Bard IVC Filters, including the Recovery Filter®, to determine whether or not the products were safe for their intended use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Bard IVC Filters, including the Recovery® Filter, so as to avoid the risk of serious harm associated with the use of Bard IVC Filters;

e. Advertising, marketing, promoting, and selling Bard IVC Filters, including the Recovery® Filter, for uses other than as approved and indicated on the product's label;

f. Failing to establish an adequate quality control assurance program used in the manufacturing of Bard IVC Filters, including the Recovery® Filter; and

g. Failing to perform adequate evaluation and testing of Bard IVC Filters, including the Recovery® Filter, when such evaluation and testing would have revealed the propensity of Bard IVC Filters to cause injuries similar to those suffered by Plaintiff.

120. As a direct and proximate result of the foregoing negligent acts and omissions of Defendants, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered from emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

121. WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENCE *PER SE*
(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

122. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

123. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and its applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale,

warning, and post-sale warning and other communications of the risks and dangers of Bard IVC Filters, including the Recovery® Filter.

124. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including but not limited to:

a. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Bard IVC Filters, including the Recovery® Filter;

b. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, by making statements and/or representations via word, design, device, or any other combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Bard IVC Filters, including the Recovery® Filter, to which the labeling and advertising relates;

c. 21 C.F.R. § 1.21, by misleading its consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Bard IVC Filters, including the Recovery® Filter;

d. 21 C.F.R. § 801, by mislabeling Bard IVC Filters, including the Recovery® Filter, as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Bard IVC Filters, including the Recovery® Filter, were associated with an increased risk of injuries due to tilting, facture, migration, and perforation;

e. 21 C.F.R. § 803, by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration, and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. 21 C.F.R. § 807, by failing to notify the FDA and/or consuming public when its Bard IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. 21 C.F.R. § 820, by failing to maintain adequate quality systems regulation, including, but not limited to, instituting effective corrective and preventative actions.

125. These statutes, rules, and regulations are designed to protect the health, safety, and well-being of consumers like Plaintiff.

126. As a direct and proximate result of Defendants' negligence *per se*, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

127. WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI: BREACH OF EXPRESS WARRANTY

128. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

129. Plaintiff, through his medical providers, purchased his Bard Recovery® Filter from the Defendants.

130. At all relevant times to this action, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Bard IVC Filters).

131. At the time and place of sale, distribution, and supply of the Recovery® Filter to Plaintiff (and to other consumers and the medical community), Defendants expressly represented and warranted that Bard IVC Filters, including the Recovery® Filter, were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they were adequately tested.

132. At the time of Plaintiff's purchase from Defendants, Bard IVC Filters, including the Recovery® Filter, were not in merchantable condition, and Defendants breached their expressed warranties, in that Bard IVC Filters:

a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;

b. Were designed in such as manner so as to result in an unreasonably high incidence of injury to the vessels and organs of its purchaser;

c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;

d. Were unable to be removed at any time during a person's life;

e. Were not efficacious in the prevention of pulmonary emboli; and

f. Carried a risk of use that outweighed any benefit.

133. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

134. WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VII: BREACH OF IMPLIED WARRANTY

135. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

136. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed Bard IVC Filters, including the Recovery® Filter.

137. Defendants impliedly warranted that Bard IVC Filters, including the Recovery® Filter, were of merchantable quality, safe and fit for the use for which the Defendants intended them and for which Plaintiff in fact used them.

138. Defendants breached their implied warranties by:

a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Bard IVC Filters would cause harm;

b. Manufacturing and/or selling Bard IVC Filters when those filters did not conform to representations made by Defendants when they left the Defendants' control;

c. Manufacturing and/or selling Bard IVC Filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;

d. Manufacturing and/or selling Bard IVC Filters that carried foreseeable risks associated with the Bard IVC Filter design or formulation which exceeded the benefits associated with that design;

e. Manufacturing and/or selling Bard IVC Filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

139. Defendants' marketing of their Bard IVC Filters, including the Recovery® Filter, was false and/or misleading.

140. Plaintiff, through his attending physicians, relied on these representations in determining which IVC Filter to use for implantation in the Plaintiff.

141. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

142. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

143. WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

VIII: NEGLIGENT MISREPRESENTATION

144. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

145. At all times relevant to this action, and as detailed above, Defendants intentionally provided Plaintiff, Plaintiff's physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted or failed to disclose material information

concerning Bard IVC Filters, including the Recovery® Filter, including, but not limited to, misrepresentations related to the following topics:

a. The safety of the Bard IVC Filters, including the Recovery® Filter;

b. The efficacy of the Bard IVC Filters, including the Recovery® Filter;

c. The rate of failure of the Bard IVC Filters, including the Recovery® Filter; and

d. The approved uses of the Bard IVC Filters, including the Recovery® Filter.

146. The information distributed by Defendants to the public, the medical community, and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

147. The foregoing representations and omissions by Defendants were false.

148. Bard IVC Filters, including the Recovery® Filter, are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

149. Further, the use of Bard IVC Filters, including the Recovery® Filter, is hazardous to the user's health, and said filters have a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries suffered by Plaintiff.

150. Finally, Bard IVC Filters, including the Recovery®, have a statistically significant higher rate of failure and injury than do other comparable IVC Filters.

151. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Recovery® Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

152. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding Recovery® Filter had not been concealed and misrepresented by Defendants.

153. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to person who are implanted with Bard IVC Filters, including the Recovery® Filter.

154. At the time, Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Recovery® Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

155. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants was the direct and proximate cause of Plaintiff's injuries as described herein.

156. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Recovery® Filter's defects.

157. WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together

with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES ALLEGATIONS

158. Plaintiff realleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

159. At all times material hereto, Defendants knew or should have known that Bard IVC Filters, including the Recovery® Filter, were unreasonably dangerous with respect to the risk of tilt, fracture, migration, and/or perforation.

160. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Bard IVC Filters, including the Recovery® Filter.

161. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of its Bard IVC Filters, including the Recovery® Filter. Defendants' conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers for their products faced, including Plaintiff.

162. At all times material hereto, Defendants knew and recklessly disregarded the fact that Bard IVC Filters, including the Recovery® Filter, have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

163. Notwithstanding the foregoing, Defendants continued to market Bard IVC Filters and the Recovery® Filter aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

164. Defendants knew of its Bard IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by the Recovery® Filter and Bard's IVC Filters.

165. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using the Recovery® Filter against its benefits.

166. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers, including Plaintiff, Plaintiff has suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including significant expenses for medical care and treatment.

167. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumer, including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

168. WHEREFORE, Plaintiff demands judgment against the Defendants as follows:

a. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and consequential damages;

b. Punitive damages in the amount sufficient to punish Defendants and set an example;

c. Disgorgement of profits;

d. Restitution;

e. Costs and Fees of this action, including reasonable attorneys' fees;

f. Prejudgment interest and all other interest recoverable; and

g. Such other additional and future relief as Plaintiff may be entitled to in law or in equity according to the claims pled herein.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests trial by jury in the above case as to all issues.

DATED: July 30, 2021.

Respectfully Submitted,

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